Reduced Residue Chemistry Data Requirements for Seed-Treatment Uses

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EPA Outline

- Introduction
- Considerations
  - All crops excluding potato seed-piece treatments
  - Potato seed-piece treatments
- Overview of Changes
- Decision Tree Overview
- Case Study: Sedaxane
- Conclusions

EPA Introduction

- EPA has released a memo that outlines reduced residue chemistry data requirements for seed-treatment uses
  - Joint effort between EPA and the Health Canada Pest Management Regulatory Agency (PMRA)
  - Performed a retrospective analysis of all seed-treatment residue data submitted to EPA and PMRA
  - Developed a tiered approach for when residue data requirements for seed treatments can be reduced
    - All crops excluding potato seed-piece treatments
    - Potato seed-piece (PSP) treatments
  - Conducted a case study

http://www.epa.gov/pesticide-registration/determining-number-field-trials-required-register-seed-treatment-uses

Considerations: All Crops Excluding Potato Seed-Piece Treatments

- **Maximum Theoretical Residue in Harvested Raw Agricultural Commodities (RACs)**
  - Calculated rates at which the maximum theoretical residue would equal 5 ppb (based solely on growth dilution of residues) and be considered non-food (NF) based on Table 1 of Guideline 860.1000
- **Foliar Use Also Registered (or Proposed) for the Crop**
  - If the crop has an existing foliar use (or a foliar use is being requested concurrently), then residue chemistry data specific to the seed-treatment use can generally be reduced or eliminated
  - Considers residues of concern (ROC) and application rates
- **Radiotracer Uptake Study**
  - Seed-treatment uses with no registered or applied-for foliar uses can often be classified as NF uses
  - Make determination using a 1X radiotracer updated study
- **Seed-treatment Rate ≤10 g ai/100 kg seed**
  - If adequate plant metabolism data are available to determine the ROC for tolerance enforcement and the application rate is ≤10 g ai/100 kg seed, then a significant reduction in data requirements is appropriate

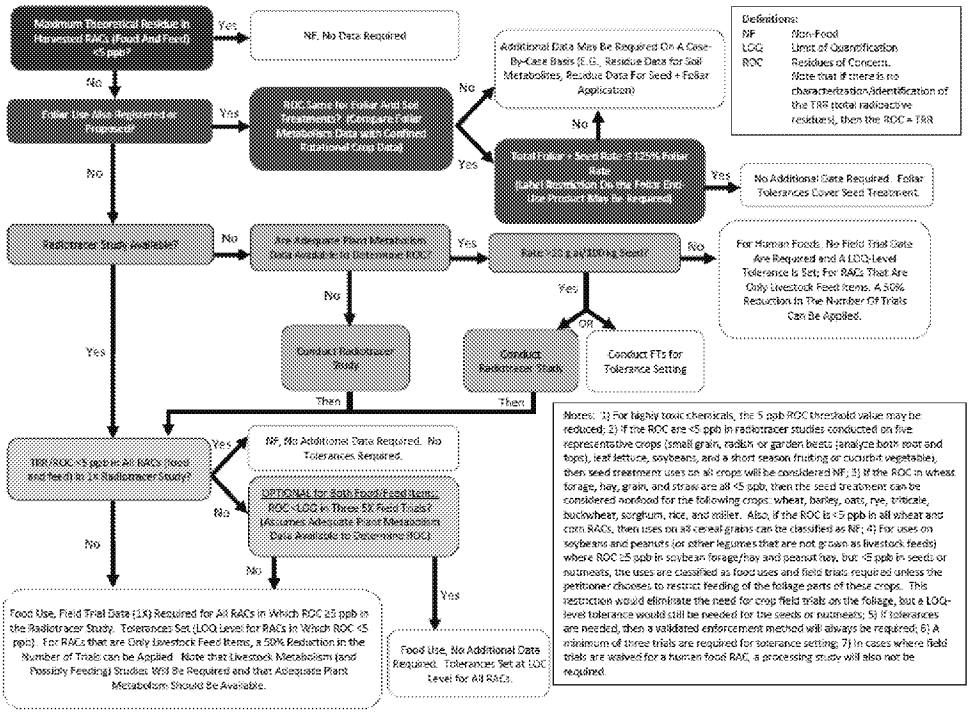
Considerations: Potato Seed-Piece Treatments

- Potato seed-piece (PSP) treatments were considered separately due to the unique nature of PSP applications
- **No Registered Potato Uses**
  - Radiotracer Uptake Study
    - Make determination using a 1X radiotracer updated study.
    - If residues of concern (ROC) are <5 ppb in potato tubers, then no further data are required, and the use is considered NF
  - Foliar or Seed-treatments Registered in Other Crops
    - The need for additional potato metabolism data may be reduced
    - PSP data are still required
  - No Other Uses Registered
    - All residue chemistry data requirements must be fulfilled
- **In-Furrow and Foliar Uses Are Registered**
  - PSP data are still required
  - If demonstrate equivalency of residues for in-furrow and PSP treatments using bridging data, then in-furrow residue data can be used to support PSP use
  - Considers if ROC are the same for foliar and soil treatments
    - Determines if additional potato metabolism data are required

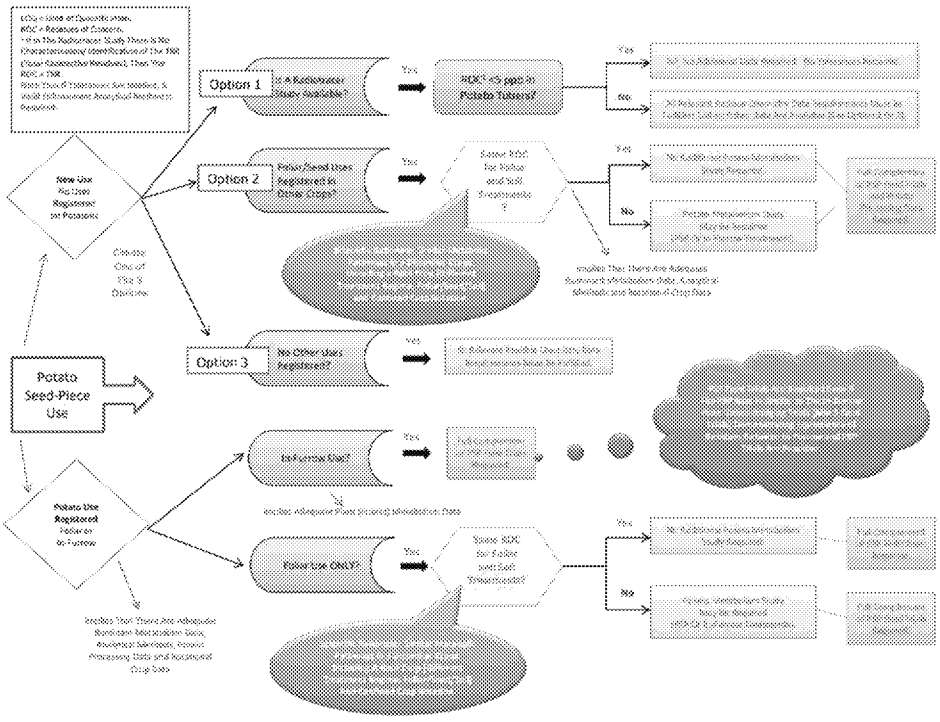
EPA Overview of Changes

- **All crops excluding potato seed-piece treatments**
  - If the crop has an existing foliar use (or a foliar use is being requested concurrently), then data specific to the seed-treatment use can generally be reduced or eliminated
  - If there are no additional metabolites of concern from soil application and the total foliar plus seed-treatment rate does not exceed 125% of the registered (or proposed) maximum seasonal foliar application rate, then additional seed-treatment field trial data are not required
  - Allows for a 50% reduction in the number of seed-treatment field trials for RACs that are exclusively livestock feed items
  - Allows for significant reductions in data requirements when seed-treatment application rates are low (≤10 g ai/100 kg seed)
- **Potato seed-piece treatments**
  - Allows for reductions in the number of field trials only when a 1X PSP radiotracer study indicates that ROCs are <5 ppb in potato tubers

EPA Decision Tree For All Crops Excluding PSP



Decision Tree For Potato Seed-Piece (PSP) Treatments



EPA Case Study: Sedaxane

- Conducted case study to illustrate potential savings resulting from use of the decision trees
- Considered three different seed-treatment petitions for the chemical sedaxane
- The following savings were estimated based on the application of the decision trees
  - 109 field trials waived
  - 40 field trials with reduced data requirements
  - Five processing studies waived

EPA Conclusions

- EPA has released a memo that outlines reduced residue chemistry data requirements for seed-treatment uses
  - All crops excluding potato seed-piece treatments
  - Potato seed-piece treatments
- The reduced seed-treatment data requirements are now in effect
- The changes in seed-treatment residue chemistry data requirements will save both petitioners and the Agency considerable resources while still obtaining the data necessary to support pesticide registrations and conduct human health risk assessments

EPA Useful Links

- Reduced Residue Chemistry Data Requirements for Seed-Treatment Uses Memo
  - https://www.epa.gov/pesticide-registration/determining-number-field-trials-required-register-seed-treatment-uses#reduced-residue
- Series 860 Residue Chemistry Test Guidelines
  - https://www.epa.gov/test-guidelines-pesticides-and-toxic-substances/series-860-residue-chemistry-test-guidelines

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Questions?